Remarks:

In the Office Action dated January 5, 2006, claims 21-41, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 21-35 and 37-41 remain in this application and claims 1-20 and 36 have been canceled.

Claims 21-41 were rejected under 35 USC §112, first paragraph as lacking an adequate written description. Though applicants respectfully disagree, the claims have been amended to recite "a copolymer of acrylic and methacrylic esters which have a low content of quaternary ammonium groups, a copolymer of ethyl acrylate and methyl methacrylate with neutral character" as suggested in the office action. In view of these amendments applicants request that this rejection be withdrawn.

Claims 36, 38 and 39 were rejected under 35 USC §112, second paragraph, as indefinite. Claim 36 has been canceled and claim 38 has been amended to delete the language "polymethacrylate derivative". Claim 39 recites a subset of the coatings recited in claim 21 and thus this rejection does not appear to apply to claim 39. In view of the above amendments and comments, applicants request that this rejection be withdrawn.

Claims 21-41 were rejected under 35 USC §103(a) as unpatentable over 2,149,052 in view of EP 0 421 921 A1 and Canadian Pat. 1,305,166. Applicants respectfully point out that the present claims indicate that the coating dissolves or is separated from the core during contact with digestive solution in the patient's

stomach. As discussed in applicant's previous response, 2,149,052 does not disclose the coatings recited in the amended claims. EP 0 421 921 discloses enteric coatings which release the drug in the intestine not the stomach as in the present invention. EP 0 421 921 (U.S. 5,096,717) teaches pamidronate granules with two coatings. The inner coating (col. 5, lines 42 – 45) contains hydroxyl propylmethyl cellulose and the outer gastric juice resistant coating contains an acrylic acid-methacrylic acid copolymer (col. 5, lines 46-50). This is different from the present invention which does not use a double coating and is not enteric. Though some of the coating agents used in the present invention do not dissolve in the acidic environment in the patient's stomach, when such coatings are used, pore forming agents are also used. The pore forming agents dissolve easily and the coating falls off during contact with digestive solution in the patient's stomach. Therefore, applicants contend that none of the cited prior art individually or in combination suggest or disclose the coating used in the present invention which dissolves or separates from the core in the patient's stomach. In view of the above discussion, applicants respectfully contend that none of the cited references disclose or suggest a method for treating bone disease by administering a formulation which contains ibandronate and a coating which dissolves or is separated from the core during contact with digestive solution in the patient's stomach and request that this rejection be withdrawn.

Applicants respectfully submit that all of claims 21-35 and 37-41 are now in condition for allowance. If it is believed that the application is not in condition

for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

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